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**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

| | |
|---|---|
| HELSINN HEALTHCARE S.A,<br><br>Plaintiff,<br><br>v.<br><br>SAGENT PHARMACEUTICALS, INC.,<br><br>Defendant. | CA. No. 2-16-cv-00173 SRC-CLW<br>CA. No. 3-16-cv-00681 MLC-DEA<br>**Filed Under Seal** |

**DECLARATION OF DONALD R. BULLOCK IN SUPPORT OF SAGENT'S MOTION**

## I. Introduction

1. I, Donald Bullock, hereby submit this Declaration in support of Sagent's motion to reopen the cases to enforce the settlement agreement with Helsinn.

2. I have personal knowledge of the facts set forth herein, or believe them to be true based on my experience in the pharmaceutical industry or upon information provided to me by others. If asked to do so, I could testify truthfully about the matters contained herein.

3. I am the Executive Vice-President of Sagent Pharmaceuticals, Inc. ("Sagent"). I have held this position since June 2016. I joined Sagent in 2007, and prior to my current role as Executive Vice-President, I was the Vice-President of Sagent from Feb. 2014 – June 2016. Prior to that, I was the Senior Director, National Sales at Sagent from May 2007 – Feb. 2014. Prior to joining Sagent, I was employed for seven years and nine months at APP Pharmaceuticals as its Eastern Area Director, and my job responsibilities were related to sales of generic injectable products in the U.S. market. Based on my current position and experience, I have knowledge concerning the generic drug industry in general as well, particularly injectable drug products.

4. Sagent's corporate office is in Schaumburg, Illinois. Sagent specializes in injectable drug products.

5. Sagent has filed two Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") for palonosetron hydrochloride injection, which reference Helsinn's New Drug Application ("NDA") No. 021372 for ALOXI®. [redacted]

6. ANDA No. 204289 obtained tentative approval on August 7, 2017, and ANDA No. 205870 obtained tentative approval on April 20, 2018. A "tentative approval" means that the drug products described in the applications are ready for final market approval but for a blocking exclusivity. Here, the exclusivity is a 180-day market exclusivity, which is granted to the first ANDA sponsor(s) to file an application with a Paragraph IV Certification to a patent listed in the Orange Book for the reference listed drug.

7. In this case, that exclusivity is shared by Dr. Reddy's Laboratories ("Dr. Reddy's"), Sandoz, Inc. ("Sandoz"), and Teva Pharmaceuticals USA, Inc. ("Teva"). Each of these companies has launched their respective generic ALOXI® product in the same dosage strength as Sagent's ANDAs, thus triggering the 180-day exclusivity. [redacted].

8. Sagent wishes to market its generic ALOXI® products in the United States [redacted]s.

## II. Market Size for ALOXI®

9. IMS Health ("IMS") is a widely-recognized company that supplies the pharmaceutical industry with sales data, and is recognized and relied on by the industry as providing reasonably accurate estimates of the size of the markets for prescription drugs.

10. Drug manufacturers, including Sagent, routinely rely on IMS data to prepare launch quantity and market share projections. I understand that, according to IMS data, ALOXI®'s sales were [redacted] (Moving Annual Total for 12 months ending Mar. 2017).

III. **Sagent's Settlement Agreement with Helsinn**

11. In early 2016, Helsinn sued Sagent for the patent infringement of several Orange Book listed patents for Aloxi® in two separate lawsuits regarding Sagent's two ANDAs.

12. On July 25, 2016, Helsinn and Sagent settled the suit and signed a License Agreement (the "Sagent Settlement") for both ANDAs, ending the litigation with Helsinn.

13. Under the terms of the Sagent Settlement, [redacted]

16. I have been advised that, Helsinn tried to enjoin Teva's launch, but the court denied that request, and that Helsinn has not similarly sought to remove Dr. Reddy's or Sandoz from the market. This strongly suggests that [redacted].

17. I have been advised that the dismissal orders for Helsinn's patent litigation cases against Dr. Reddy's and Sandoz expressly [redacted]. Therefore, because Helsinn has failed to [redacted].

IV. **Uncertainty of Launch Date**

[redacted]

[redacted]

V. **Significant lead time to prepare for a Commercial launch**

[redacted]

[redacted]

28. These losses of revenue would amount to a significant percentage of Sagent's revenue in the United States.

29. Sagent has forecasted that [redacted], it may generate a potential revenue of [redacted] However, if

the launch is unnecessarily delayed [redacted] then the projected revenue will erode almost completely.

30. In other words, if Sagent's launch is unnecessarily delayed from no later than [redacted] then all of the major contracts with GPOs and IDNs will have been awarded to other competitors and the prices of generic ALOXI® will have decreased to a point that a small, non-fully integrated company like Sagent would not be able to compete at all. Sagent would lose the initial [redacted] investment in the preparation of its ANDAs products and will end up with [redacted].

31. Further, only the following three other ANDA sponsors have tentative approval at present: Aurobindo Pharma Ltd.; Akorn, Inc.; and Somerset Therapeutics, LLC. I understand Helsinn sued all three for patent infringement and have settled their cases. As of today, they are the only other ANDA sponsors able to receive final FDA approval (and presumably launch under their agreements with Helsinn) at the same time as Sagent upon expiration of the 180-day exclusivity. Additional competition is expected in the future, as Helsinn is known to have sued at least fourteen other ANDA sponsors. That means an additional eleven other ANDAs (including the five to seven, as estimated) could also receive final approval in the future, assuming their applications met FDA requirements, and such increased competition harms Sagent by decreasing the value of the opportunity of [redacted].

32. As noted above, should Sagent's launch be delayed until [redacted], the projected revenue is forecasted to decrease from [redacted] to erode to a point that Sagent may not be able to recoup its research and development costs associated with preparing

and filing the ANDAs, even assuming Sagent were able [redacted], which it likely will not be able to do so.

VI. [redacted] **Sagent Settlement**

33. [redacted] Helsinn and Sagent memorialized it in the Sagent Settlement. Helsinn is required [redacted] Sagent Settlement [redacted].

I declare under penalty of perjury that the foregoing is true and correct.

Dated: May 11, 2018

Donald R. Bullock
Executive Vice-President
Sagent Pharmaceuticals, Inc.